4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1157]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0891. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

OMB Control Number 0910-0891--Extension

OMB's Office of Information and Regulatory Affairs has issued memoranda that provides an overview of administrative flexibilities available to assist Agencies in complying with their statutory obligations under the PRA. Among these flexibilities is use of a generic clearance for certain information collection activities. A generic clearance may be appropriate when (1) the need for the data collection can be evaluated in advance, as part of the review of the proposed plan, but (2) the Agency cannot determine the details of the specific individual collections until a later time. Generic clearances cover collections that are voluntary, low-burden, and uncontroversial.

This generic clearance supports research intended to help the Center for Food Safety and Applied Nutrition understand stakeholders' perceptions, attitudes, motivations, and behaviors. To ensure that communications activities have the highest effect, we will conduct research and studies relating to the control and prevention of disease and the safety and health of the public. FDA is requesting OMB approval for the use of this generic collection of information that allows FDA to use qualitative social/behavioral science data collection techniques (i.e., individual indepth interviews, small group discussions, focus groups, and observations) to better understand stakeholders' perceptions, attitudes, motivations, and behaviors regarding various issues associated with food and cosmetic products, dietary supplements, and animal food and feed. Understanding these consumers', manufacturers', and producers' perceptions, attitudes, motivations, and behaviors plays an important role in improving FDA's communications that impact these various stakeholders and assists in the development of quantitative study proposals, complementing other important research efforts in the Agency.

To obtain approval for an individual generic submission collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (e.g., a copy of the interview or moderator guide, screening questionnaire).

Selection for potential respondents is done via a screening process to match the best possible respondent to each individual generic submission. Respondents to individual requests made under the generic clearance, once approved by OMB, may include a wide range of consumers and other FDA stakeholders, such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Participation is voluntary.

In the *Federal Register* of April 10, 2023 (88 FR 21193), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was not responsive to the four collection of information topics solicited and therefore will not be discussed.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Type of Interview	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Individual Indepth Interview Screening	4,800	1	4,800	0.08 (5 minutes)	384
Individual Indepth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening	10,800	1	10,800	0.08 (5 minutes)	864
Focus Groups/Small Group Discussion	3,600	1	3,600	1.5	5,400
Observation Screening	720	1	720	0.08 (5 minutes)	58
Observations	144	1	144	2	288
Total			20,464		7,394

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The collections we have conducted under this generic collection of information have informed and helped us better understand stakeholder perceptions, attitudes, motivations, and behaviors to help us improve our communications to them.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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